DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

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Certifier A Dedens

Ophthalmic and Topical Dosage Form New Animal Drugs; Moxidectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health. The supplemental NADA provides for topical use of a 0.5 percent moxidectin solution on cattle for treatment and control of infections of additional life stages and species of gastrointestinal roundworms.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Janis Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed supplemental NADA 141–099 that provides for use of Cydectin® (moxidectin) 0.5% Pour-On for Beef and Dairy Cattle at 500 micrograms moxidectin per kilogram of body weight for treatment and control of infections of additional life stages and species of gastrointestinal roundworms. The supplemental NADA is approved as of June 18, 2001, and the regulations are amended in 21 CFR 524.1451 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support

approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning June 18, 2001, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1451 is amended by redesignating paragraph (d) as paragraph (e), by removing the last sentence of newly redesignated paragraph (e)(3), by adding new paragraph (d), and by revising newly redesignated paragraph (e)(2) to read as follows:

K. Banks OFR 8-30-01

§ 524.1451 Moxidectin.

* * * * *

(d) *Special considerations.* See § 500.25 of this chapter.

(e) * * *

(2) *Indications for use.* Beef and dairy cattle: For treatment and control of internal and external parasites: gastrointestinal roundworms (*Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult and L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *Cooperia oncophora* (adult and L4), *C. pectinata* (adult), *C. punctata* (adult and L4), *C. spatulata* (adult), *C. surnabada* (adult and L4), *Bunostomum phlebotomum* (adult), *Oesophagostomum radiatum* (adult and L4), *Nematodirus helvetianus* (adult and L4)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (*Hypoderma bovis*, *H. lineatum*); mites (*Chorioptes bovis*, *Psoroptes ovis* (*P. communis* var. *bovis*)); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Bovicola* (*Damalinia*) *bovis*); and horn flies (*Haematobia irritans*). To control infections and to protect from reinfection with *H. placei* for 14 days after treatment, *O. radiatum* and *O. ostertagi* for 28 days after treatment, and *D. viviparus* for 42 days after treatment.

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Dated: 8/24/01

August 24, 2001.

Claire M. Lathers

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